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Guidance for the Reregistration of Products Containing Maleic Hydrazide as the Active Ingredient

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Guidance for the Reregistration of Pesticide Products Containing MALEIC HYDRAZIDE as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

Maleic Hydrazide

OPP Shaughnessy Numbers: 051501, 051502, & 051503

AS THE ACTIVE INGREDIENT

OPP Number: 0381

CAS Number: 123-33-1 and 28382-15-2

June 30, 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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I. GLOSSARY OF TERMS AND ABBREVIATIONS

ADI:	Acceptable daily intakes
ae:	Acid equivalent
ai:	Active ingredient
CAS:	Chemical Abstracts Service (Number)
CSF:	Confidential Statement of Formula
DEA:	Diethanolamine salt of maleic hydrazide
DMF:	Dimethyl formamide
EC:	Emulsifiable concentrate
EEC:	Estimated Environmental Concentration
EP:	End-use product
EPA	The Environmental Protection Agency, also "the Agency"
F_1, F_2:	Refers to the generation in a multigeneration reproduction study
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
g/kg:	Grams per kilogram
HDT:	Highest dose tested
IRDC:	International Research and Development Corporation
K:	Potassium
Kdes:	Freundlich desorption value
Kads:	Freundlich adsorption value
LC_{50}:	(Median lethal concentration) - A statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water per weight of feed (e.g., mg/L or ppm).

LD_{50}:	(Median lethal dose) - A statistically derived single dose that can be expected to cause death in 50 percent of test animals when administered by the route indicated, expressed as weight of substance per unit of weight of test animal (e.g., mg/kg).
LDT:	Lowest dose tested
LEL:	Lowest-effect level
LOEL:	Lowest-observed-effect level
MATC:	Maximum allowable toxic concentration
mg/kg/bwt/ day:	Milligrams per kilogram of body weight per day
MH:	Maleic hydrazide including potassium salt
MOS:	Margin of Safety
MP:	Manufacturing-use product
MPI:	Maximum permissible intake
MRID:	Master Record Identification (Number) - EPA's system of tracking studies used in support of registration
NOEL:	No-observed-effect level
NPDES:	National Pollution Discharge Elimination System
OES:	Office of Endangered Species, U.S. Fish and Wildlife Service
OPP:	The Office of Pesticide Programs
PADI:	Provisional acceptable daily intake
PD 1:	Position Document 1
ppb:	Parts per billion
ppm:	Parts per million
RAC:	Raw agricultural Commodity
RPAR:	Rebuttable Presumption Against Registration
SC/S:	Soluble concentrate/solid

SC/L: Soluble concentrate/liquid

Scapulae: Shoulder blade

TGAI or technical: Technical grade of the active ingredient

TMRC: Theoretical Maximum Residue Contribution

>: Greater than

<: Less than

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and use Index may be obtained from the National Technical Information Service (NTIS), ATTN: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 or by phone (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggest possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as a product is registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICALS

The following chemicals are covered by this Registration Standard:

Common Name: Maleic Hydrazide, Diethanolamine salt, or
Potassium salt

Chemical Names: 6-Hydro-3(2H)-pyridazinone or
1,2,-Dihydro-3,6-pyridazinedione

CAS Number: 123-33-1

OPP Shaughnessy Numbers: 051501, 051502, and 051503

Empirical Formula: $C_4H_4N_2O_2$

Trade Names: Drexel Sucker-Stuff, Super Sucker Stuff, Retard, Burtolin, Decut, Drexel Sprout Stop, Fair 2, Fair Plus, KMH, Maintain 3, Malazide, Mazide, Regulox W, Regulox 50W, Stuntman, Super-De-Sprout, Vondalhyde, Vondrax, Royal MH-30, Royal MH-30SG, Royal Slo-Gro, Malazide Slo Gro.

Year of Initial Registration: 1952

B. USE PROFILE

Type of Pesticide: Herbicide and plant growth regulator.

Registered Uses: Terrestrial food crops, nonfood crops, and terrestrial noncrop lands.

Predominant Use: Sucker control for tobacco, sprout inhibition in stored onions and potatoes, frost protection in citrus, and growth retardent in turf and roadside maintenance.
Herbicidal activity on quackgrass, wild onions, and wild garlic

Mode of Activity: A Uracil antimetabolite

Formulation: 90, 95, 97, and 99 percent TGAI
0.66 and 2.25 lb ae/gal EC
0.6, 1.5, 2.0, 2.25, and 2.5 lb ae/gal SC/L

Method of Application: Primarily as a foliar spray, with some use by tree injection.

C. HISTORY

MH was synthesized and determined to have growth inhibiting properties in 1947. The chemical was first registered in 1952. In October 1976 it was referred to the Agency for RPAR. The referral was based on laboratory studies which indicated that MH induced oncogenic, mutagenic, and reproductive effects. In October 1977, the Agency initiated an RPAR review by publishing a PD 1 for MH. The PD 1 described studies which met or exceeded the RPAR criteria for oncogenic, mutagenic, and reproductive effects.

The Agency did not issue the PD 2/3 for maleic hydrazide because of the absence of adequate risk data for oncogenic, mutagenic and reproductive effects. Agency scientists could not adequately assess the risk potential of maleic hydrazide because of the paucity of valid toxicological information and conflicting results within each data base. To fill these data gaps, the Agency required all MH registrants to submit data regarding the reproductive effects and mutagenic potential of DEA-MH and K-MH pursuant to the authority of section 3(c)(2)(B) of FIFRA. The Notice announcing these data requirements for MH was sent to all registrants on August 14, 1980.

The manufacturers agreed to submit the required data on K-MH on February 26, 1981. Because manufacturers of the DEA-MH decided not to submit the required additional data, the Agency suspended all DEA-MH registrations in November 1981. The suspension may be lifted at such time that there is compliance with the data request.

The information submitted in response to the Data Call In Notice was evaluated. The Agency determined that two of three RPAR triggers (oncogenicity and reproductive effects) were not supported. Although mutagenicity was an initial RPAR trigger, our criteria for special review in this area area has become more rigorous and focused on confirmation of effects in mammalian systems. The limited mutagenicity data available is generally negative. Additional data are required by this document.

During the evaluation of the available oncogenic studies, the agency determined that consideration of hydrazine contamination might help determine the oncogenic potential of maleic hydrazide. The Agency reached this hypothesis because two similar studies showed different results: Epstein and Mantel (1968) reported an increased incidence of hepatomas, where as Cabral at al.(1981) reported no significant increase in tumor incidence. A primary difference between the two studies was the level of hydrazine contamination in the MH they used: 4000 ppm in the Epstein study and less than 1 ppm in the study by Cabral.

Several studies show a definite relationship between hydrazine and tumor induction. The Agency used a study by Biancifiori in which a dose related induction of hepatomas was observed and the one hit model was used to determine the lifetime risks to humans. In calculating the risk from maleic hydrazide it was assumed that the hydrazine contamination is 15 ppm, the highest level reported in currently registered technical MH products. The estimated oncogenic risks did not cause concern and the Agency consequently decided to terminate the RPAR review of MH at that time.

The Agency published a Position Document (PD-4) for Maleic Hydrazide in June 1982. The final determinations were to terminate the RPAR to allow the continued use of potassium MH, and to establish an acceptable limit of hydrazine at 15 ppm in technical grade products to avoid the potential for unreasonable adverse effects.

III. AGENCY ASSESSMENT

A. SUMMARY SCIENCE STATEMENT

MH has low acute toxicity (Toxicity Category III) for primary eye irritation and is in Toxicity Category IV for acute oral, acute dermal, and primary dermal irritation. MH caused no adverse reproductive effects; was not oncogenic to mice; and not mutagenic. The teratology study in rabbits had a teratogenic NOEL of 100 mg/kg/day (malformed scapulae occurred in the mid and high dose). An exposure assessment was performed and it was determined that MOSs were < 100 for mixer/loaders, therefore, of potential concern. The Agency is requesting additional teratology data to fully define the teratogenic effect. To reduce exposure to applicators this standard requires that the label be amended to require protective clothing while handling, applying, mixing or loading the chemical.

MH was stable to hydrolysis and photodegradation in soil. It photodegraded in buffered aqueous solutions at pH 5, 7, and 9. MH was very mobile in five soils and has a low potential to bioaccumulate in fish. Additional persistance and leaching data are needed to evaluate MH's potential to contaminate ground water.

MH is considered practically nontoxic to birds, aquatic invertebrates, freshwater fish, or honey bees. Endangered animal species are not expected to be adversely affected by the use of MH. Since no endangered plant species are listed for tobacco cropland, citrus, apples, potatoes and onions or canberries, little risk is expected to endangered plants from these uses. A hazard assessment for the right-of-way use is deferred until the Agency develops the non-cropland cluster.

B. TOXICOLOGICAL CHARACTERISTICS

There are three forms of maleic hydrazide registered, the technical, the K salt, and the DEA salt. All DEA salt registration were suspended in 1981 for failure to submit data in response to a data call in notice. Some of the data discussed below are on the parent and some of it are on the K salt. For this Standard, they will be considered equivalent.

Even though the DEA salt is suspended, the suspension may be lifted at such time that manufacturers comply with the data request.

Because there may be qualitative or quantitative differences in the behavior of the DEA salt due to the DEA moiety, and because the DEA moiety itself may be oncogenic or cause other effects not seen with the other salts, a separate set of toxicology studies are required for the DEA salt. Refer to the discussion below, and Table A-2, for specific data requirements.

Acute Toxicity

Acute oral and acute dermal toxicity studies place MH in Toxicity Category IV with an acute oral toxicity > 5 g/kg and an acute dermal toxicity > 20 g/kg. In the dermal toxicity study, the test material caused only very slight erythema and edema resulting in a Toxicity Category IV classification. These requirements are fulfilled for MH but are required for the MH-DEA salt.

The available acute inhalation study did not provide enough detail for evaluation, therefore an acute inhalation study is needed for both MH and MH-DEA.

There are no data available on primary dermal sensitization properties. Therefore, dermal sensitization studies for both MH and the MH-DEA salt are needed.

Subchronic Toxicity

There are no data available on subchronic oral, dermal, or inhalation toxicity. The data requirement for subchronic oral toxicity is waived for the parent, the K salt, and the DEA salt because chronic studies are required for a rodent and a nonrodent.

A 21-day dermal toxicity study is required for both MH and the DEA salt. Ninety-day dermal subchronic studies are not required for either the DEA salt or MH because existing use patterns do not involve purposeful or prolonged dermal exposure.

Subchronic inhalation studies are not required at this time, but may be required once the requested residue data on tobacco are received and reviewed.

Neurotoxicity

There are no data available for acute delayed or subchronic delayed neurotoxicity for either MH or the DEA salt. Acute delayed neurotoxicity studies are not required because MH and its salts are not organophosphates. Subchronic neurotoxicity studies are not required because acute neurotoxicity testing is not required and there is no evidence of neurotoxicity in mammalian species.

Chronic Toxicity

The available chronic feeding study in rats is inadequate because a NOEL was not established for renal toxicity and the raw data were not available for review. The available data indicate that the NOEL is < 500 mg/kg (LDT). There are no chronic feeding studies available for nonrodents. Chronic feeding studies are required for both MH and the DEA salt on both rodents and nonrodents.

Oncogenicity

The oncogenicity potential in rats could not be adequately determined because raw data (especially histopathology) were unavailable for review. Therefore, oncogenic studies with rats are required for both MH and the DEA salt of MH.

Two recent oral oncogenicity studies are available to evaluate the oncogenic potential of MH. These studies collectively indicate that MH is not oncogenic in mice. These studies are discussed below.

In a mouse oncogenicity study with common control performed by Cabral and Ponomarkov, group I mice were fed an oral dosage of 510 mg/kg MH daily for 125 weeks; group II mice were dosed as follows: one group of mice received several subcutaneous dosages totaling 55 mg/kg MH in the vehicle tricaprylin applied during the first three weeks after birth and a second group of solvent control animals received the same amount of pure tricaprylin over the same period. Both subgroups were sacrificed after 125 weeks. Untreated concurrent control animals were shared by both oral group I and subcutaneous treatment groups. No compound-related effects were seen in group I. In group II, male mice had a statistically significant increase in liver tumors when compared with untreated control males, but the increase was not statistically different from the solvent control males. No evidence of compound-related oncogenic effects was seen in females. Because the group II results could be caused by either the MH, a low level of hydrazine, or an interaction between MH or hydrazine and the tricaprylin, group II could not be definitely interpreted. Because group II could not be interpreted correctly and group I used only one dosage, this study was classified as Supplementary data.

In a second study performed by IRDC, mice were fed oral dosages of 0, 150-200, 500-600, 1600-1800 mg/kg/day for their lifetime. Hemangiomas and lung adenomas and carcinomas in females were considered to be of potential concern. When the hemangiomas from all sites were combined, as is appropriate for this data set, their incidence was judged not to be significant.

While there was a significant trend in lung adenomas and/or carcinomas, there were no significant pair-wise comparisons between exposed and control mice, and the incidence of these tumors were within the historical control range. Therefore, MH was not considered oncogenic in mice.

Both group I of the Cabral study and IRDC study used mice, dosed orally for their lifetime. In both experiments, detailed gross and microscopic pathologic examinations were performed on a standard set of tissues and organs and appropriate statistical analysis were performed on the data. The two studies were considered to be "supplementary" on their own, but collectively provide an adequate data base to determine that maleic hydrazide is not oncogenic to mice. No additional data are needed on this potential effect for maleic hydrazide technical or the K salt.

An oncogenic study with mice is required for the DEA salt of MH.

Teratogenicity

No data are available to determine teratogenic effects in rats. Therefore teratology studies are required in rats for MH and the DEA salt of MH.

A teratology study in rabbits fed K salt MH dosages of 0, 100, 300, and 1000 mg/kg/day is available. No signs of maternal toxicity were seen; therefore, the maternal NOEL is 1000 mg/kg/day (HDT). Malformed scapulae were seen in 4 out of 99 animals at the mid-dose and 2 out of 107 animals at the high-dose. Therefore the teratogenic NOEL is 100 mg/kg. This is a rare malformations seen in only 1 fetus out of 1586 fetuses in the historical control. This effect was considered significant. Therefore the Agency performed an applicator exposure assessment. Based on the exposure estimate, the MOSs for dermal exposure for open-pour mixer/loaders for most applications would be < 100 and a potential concern. Based on this concern, additional information on parentage of affected rabbits is requested. Additional information may be required once this information and the rat teratology study are reviewed. Until this is resolved a label statement requiring protective clothing will be added. Refer to labeling section for the wording of this label statement.

A teratology study with rabbits is required for the DEA salt of MH.

Reproduction

The available two-generation study fulfills this requirement for MH. No adverse effects on reproduction were noted in male or female rats fed dosages of 0, 75, 750, and 2250 mg/kg. The maternal toxic NOEL is 750 mg/kg with a LOEL of 2250 mg/kg (decreased parental weights). The fetotoxic NOEL is 750 mg/kg with a LOEL of 2250 mg/kg (decreased bodyweights).

A two-generation reproduction study in rats is required for the DEA salt of MH.

Mutagenicity

No mutagenicity data are available for the DEA salt of MH; therefore, studies are required to satisfy gene mutation, chromosomal aberrations, and other mechanisms of mutagenicity.

A mutagenicity study of sex-linked recessive lethal gene mutations in Drosophila revealed no sex-linked recessive lethal mutations at cytotoxic doses from 0.4 to 1.0 percent of 26.7 percent K-MH in water. This fulfills the gene mutation requirement for MH. No data are available on the mutagenicity of MH for chromosomal aberrations or other mutagenic mechanisms, therefore these data are required.

Metabolism

There are no metabolism studies available for MH or the DEA salt; therefore, rat studies of the absorption, distribution, metabolism, and excretion after acute and repeated exposures are required for both MH and the DEA salt of MH.

C. PHYSIOLOGICAL AND BIOCHEMICAL BEHAVIOR CHARACTERISTICS

Absorption of MH by roots and leaves is a function of cell turgidity with most effective absorption occurring when soil moisture is at field capacity and relative humidity is high. Once absorbed, MH is rapidly translocated to leaves and growing shoots.

The mechanism of pesticide action for MH is believed to be as a uracil antimetabolite which interferes with cell division, plant growth, and maturation. It also affects respiration through inhibition of one or more dehydrogenases.

Available tobacco metabolism data on MH indicate that the major residues of MH in plants are the parent and its beta D-glucoside conjugate. Additional plant metabolism data are required.

No data are available for metabolism of MH in animals. Metabolism studies using ruminants and poultry are required.

D. ENVIRONMENTAL CHARACTERISTICS

MH was stable to hydrolysis in buffered solutions at pH 3, 6, and 9 when maintained at 45 °C for 61 days and 80 °C for 30 days, and was stable to photodegradation in soil after 17-day irradiation by artificial light. MH photodegraded in buffered aqueous solutions at pH 5, 7, and 9 with half-lives of 58 days at pH 5 and 7 and 34 days at pH 9 when irradiated by artificial light. Unaged MH was very mobile in a silt loam soil, a sandy clay loam soil, a sandy loam soil, and two sandy soils with Kads values of 0.14 to 2.61 and Kdes values of 0.39 to 14.45. Unaged MH was very mobile in soil columns of clay loam and sandy loam soils. Aged MH was very mobile in soil columns of sandy loam and clay loam soils and very mobile in sandy loam soil with Kads value of 2.37 and the Kdes value was 2.74. MH dissipated in a field application with a half-life of 3 to 7 days from the upper 6 inches of clay loam soil.

MH has a low potential to bioaccumulate in fish with octanol/water partition coefficient values of < 0.6 at pH 6, 7, and 9.

The available data are inconclusive for potential to leach into ground water because of lack of information on persistence of degradates under aerobic/anaerobic soil conditions. The chemical is persistent in water since it is stable to hydrolysis. The chemical is very mobile in five soils. Available field persistance data do not adequately define the depth of leaching and are inconclusive. The full leaching potential of MH cannot be determined until persistence data are submitted and evaluated. Once the leaching potential of MH is determined, a ground water monitoring study may be required.

The data requirements for hydrolysis, photodegradation in soil and fish accumulation are satisifed. The following data are required to fully assess the environmental fate of MH: photodegradation in water, aerobic and anaerobic soil metabolism studies, terrestrial field dissipation study, a soil column and adsorption/desorption studies with aged MH, and a confined accumulation study on rotational crops with wheat or another small grain. Additional data may be required if requested studies indicate the need for additional data.

E. EXPOSURE AND RISK

During review of data an applicator exposure assessment was performed because of rare teratogenic effects (refer to discussion of teratogenic effects) seen in rabbits. The exposure estimates were based on data available from the public literature for individuals wearing long sleeved shirts and long pants at all times and chemical resistant gloves during mixing loading. The estimates were not adjusted for dermal absorption of MH and, therefore, assume 100% dermal absorption. The MOS for open-pour mixers-loaders were less than 100. The MOS for closed system mixer loaders were greater than 100. The MOS for pilots were greater than 1000. Those MOS's of less than 100 are of potential concern (Standard Evaluation Procedure for Teratology Studies, June 1986). To evaluate these potential concerns, the Agency is requiring that additional information on parentage of affected animals be submitted and that the labeling be amended to require protective clothing. Refer to labeling section for wording required. The Agency is planning a high priority on the review of the rat teratology study.

Reentry data are not required for MH because current use patterns (7- to 70-day PHI application to plants at early growth stage) indicate little likelihood of exposure or low exposure at this time, and the placement of the chemical in Toxicity Category IV for acute oral and acute dermal toxicity indicate minimal risk to humans.

F. ECOLOGICAL CHARACTERISTICS

Terrestrial Organisms

Based on acute oral toxicities of > 4640 mg/kg/day (technical) and > 2250 (K salt) to mallard ducks, MH technical and K salt present very low toxicity to avian species on an acute oral basis. Available data indicate that the 8-day dietary toxicity of MH technical is > 10,000 ppm for both mallard ducks and bobwhite quail and that the 8-day dietary toxicity for the MH K salt is > 5620 ppm for mallard ducks. Based on these data, the technical and K salt of MH present very low toxicity to avian species on a dietary basis. The requirements for acute oral toxicity and dietary toxicity tests with avian species have been satisfied. No data are required for the DEA salt because of the low order of toxicity to avian species of the technical and K salt. Avian reproduction studies are not required because the only repeated use pattern of MH is small (golf course fairways) and the acute oral and dietary toxicity values for birds show it to present very low toxicity.

Mammals are not expected to encounter risk from the use of MH or the K salt based on low acute toxicity to rats.

The timing of application of MH on tobacco, the major agricultural use, is at the time of full flower presenting exposure to honey bees in the area. However, with a toxicity value of > 36.26 ug/bee, MH presents very low toxicity to honey bees; therefore honeybees in the area are not at risk.

Aquatic Organisms

Based on 48-hour acute toxicities of 107.5 ppm (technical) and 1000 ppm (K salt), MH is considered to present very low toxicity to freshwater invertebrates. There are no data requirements for the DEA salt based on the low order of toxicity of MH (technical and K salt) to aquatic organisms. The requirement for an acute toxicity study with freshwater invertebrates has been satisfied.

Based on acute toxicities of 1435 ppm (technical) to rainbow trout, 1608 ppm (technical) to bluegill and > 1000 ppm (K salt) to rainbow trout, MH (technical and K salt) are considered practically nontoxic to both coldwater and warmwater fish. There are no data requirements for the DEA salt based on the low order of toxicity of MH and the K salt to fish. The requirements for acute toxicity testing with freshwater fish are satisfied.

The use of MH as a foliar application on tobacco and roadway rights-of-way will not cause hazard to aquatic species from runoff. The EEC for foliar application of MH is 12 ppb. The risk of MH to aquatic species inhabiting those waters is low with a safety factor of over 1000 for aquatic invertebrates, the most sensitive species.

Plant Protection

There are no data available for MH concerning phytotoxicity. Because MH is a plant growth retardant and there is no previous plant data base, the Agency assumes possible hazard to endangered plant species. Therefore, Tier I nontarget area phytotoxicity testing is required.

Endangered Species

Because MH is a plant growth retardant, the Agency assumes hazard to any endangered plants occurring in areas where MH is used. There are no endangered plants listed as occurring in tobacco cropland, in citrus, apples, potatoes, onions, or cranberries, therefore there is no risk to endangered plants from use of MH on these sites. Evaluation of hazard to endangered plants from use on right-of-ways will await evaluation of all pesticides in the noncrop cluster.

Because of the low toxicity of MH to mammals, avian species, aquatic species, and the low potential for exposure to MH, endangered animal species are not expected to be affected by use of MH.

G. PRODUCT CHEMISTRY

The Agency has determined that product chemistry data for all technical and MPs must be submitted for each pesticide because new requirements have been introduced and previously submitted data must be updated. Therefore, a complete set of product chemistry data is required for the TGAI and MPs.

During the RPAR review the Agency determined that hydrazine, a contaminant of maleic hydrazide products, is itself an oncogen and that the amount of hydrazine occurring in technical products must be ≤ 15 ppm. Refer to History Section for details.

Available data indicate that nitrosamines may occur in EPs containing the DEA salt of MH. Because some nitrosamines are known carcinogens, testing for nitrosamines will be required for all end use products containing the DEA salt.

H. TOLERANCE REASSESSMENT

Tolerances Issued

Tolerances are established for residues of the herbicide and plant regulator MH (1,2-dihydro-3,6-pyridazinedione)(40 CFR 180.175) in or on the RACs cranberries at 15.0 ppm; onions, dry bulb at 15.0 ppm; and potatoes at 50.0 ppm.

A food additive tolerance is established for residues of the herbicide and plant regulator MH (1,2-dihydro-3,6-pyridazinedione) (21 CFR 193.270) on potato chips at 160 ppm as a result of the pesticide application to the growing potato plant.

Canadian tolerances and Codex MRL (CXL) of 50 ppm on potatoes and 15 ppm for onions are established for MH.

No Canadian tolerances or Codex MRL are established in cranberries, citrus, or tobacco and no Codex MRL is established in apples. Therefore, no compatibility questions exist with respect to Codex MRL. A Canadian tolerance of 7 ppm is established for residues of MH in apples.

Residue Data

The residue data reviewed in support of these tolerances, and the data gaps are discussed below are discussed below.

1. Available tobacco metabolism data on MH indicate that MH is absorbed rapidly and translocated to leaves and growing shoots. The major metabolite in tobacco is the glucose conjugate of the parent, 1,2-dihydro-3,6-pyridazinedione glucoside. Additional plant metabolism data in cranberries, onions, and potatoes are required.

2. Data from a cattle feeding study indicate that residues of MH transfer to animal tissue. Livestock metabolism data are not available and are required.

3. The available data for potatoes and dry bulb onions indicate that the residues will not exceed the established tolerances following registered use of SC/L K salt formulation. Additional data are required to evaluate the use of the EC K salt formulation on potatoes and onions. A processing study is required on potatoes.

4. Available residue data on cranberries support the tolerance for cranberries. No additional data are required.

5. No data are available for the preharvest use of the DEA salt of MH on potatoes and onions. Residue data will be required for the DEA salt for use on potatoes and onions should any registrant comply with the data requirements which resulted in the suspension.

6. No data are available to support a nonfood classifcation for the use of MH on nonbearing apples. Data are required and if residues are detectable on the fruit, tolerances must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products.

7. Available data are insufficient to support a nonfood use classification for use of MH on nonbearing citrus. Residue data are required and if residues are detectable on the fruit, tolerances must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products.

8. The available data on tobacco are not sufficient to adequately assess the exposure of man to residues of MH.

Available data do indicate that MH residues of > 0.1 ppm are likely to be present in tobacco and indicate the potential for residues of hydrazine, nitrogen gas, ammonia, amines, hydrogen gas, nitriles, and nitrogen heterocyclic compounds following pyrolysis of MH. Residue data are required, pyrolysis products must be characterized, and the level of residues occurring in smoke quantified.

9. Animal metabolism data are needed to show whether tolerances for MH or its metabolites are required in animal commodities. If there is a need for a tolerance EPA will also require data depicting the stability of MH or its metabolites in animal commodities during the storage of animal commodities.

10. Adequacy of analytical methodology will be determined once requested method validation data are submitted. If the required animal metabolism data reveal metabolites of concern, validated analytical methods for residue data collection and enforcement will be required.

Toxicology Data

The toxicology data considered in support of the tolerances include a chronic study in rats with a LOEL of 500 mg/kg for renal effects, a teratology study in rabbits with a teratogenic NOEL of 100 mg/kg, and a reproduction study in rats with a NOEL of 750 mg/kg. Refer to the toxicology section above for detailed information on these studies and additional requirements.

The data gaps in the current data base relevant to a reference dose (PADI) are a chronic study in a nonrodent species (dog) and a rat teratology study. The Toxicology Branch RfD Committee derived the reference dose of 0.5 mg/kg/day from the LOEL of 500 mg/kg for renal dysfunction in the rat by applying a total uncertainty factor of 1000 (a factor of 100 for inter- and intraspecies differences and a factor of 10 because the LOEL was used). Existing tolerances produce a TMRC of 0.085 mg/kg/day which occupies 17 percent of the PADI.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITION AND RATIONALE

1. None of the criteria listed in 40 CFR 154.7 have been exceeded for MH. Therefore, no referral to Special Review is being made at this time.

Rationale: Based on available information, MH does not exceed the risk criteria for adverse effects in 40 CFR 154.7. Available data indicate that MH does not pose a risk of serious injury to humans, avian species, or aquatic organisms.

2. The Agency will not approve any significant* new food uses of MH until additional residue chemistry data are available to assess existing uses.

Rationale: It is Agency policy not to establish significant new uses where major data gaps exist. When additional data are evaluated the Agency will determine whether significant new food uses may be established.

3. The Agency is requiring that labeling on all EPs require protective clothing: long sleeve shirt, long pants and chemical resistant gloves at all times while handling, applying, mixing, or loading this chemical.

Rationale: Rare teratogenic effects were observed in test animal. Exposure estimates for dermal exposure were based on individuals wearing long sleeve shirts, long pants, and chemical resistant gloves and resulted in some margin of safety estimate of less than 100. Refer to teratology and exposure sections in Part III.B. and E. for additional information and Part IV.D. for specific wording.

4. The Agency is requiring that additional leaching, aerobic/anaerobic soil metabolism, and dissipation data be submitted to fully define the potential of MH to leach into groundwater.

Rationale: The available data are insufficient to define the potential of MH to leach and contaminate ground water. Refer to Part III.D. for additional information.

5. The Agency is requiring that additional information be submitted on the rabbit teratology study and that a rat teratology study be completed within 12 months.

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*"Significant new uses" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the TMRC of > 1 percent.

Rationale: A rare teratogenic effect was seen in the rabbit teratology study; therefore, additional information on parentage of affected animals is needed to fully define this effect. This information, along with the rat teratology study, will be used to determine if additional data on teratogenicity are needed and additional regulatory restrictions are warranted. Refer to teratology section of Part III.B. for additional information.

6. The Agency has determined that a full battery of toxicology studies will be necessary for the DEA salt of MH should manufacturers comply with data requirements that reresulted in suspension. Refer to Part III.B. for a detailed listing of requirements.

Rationale: The Agency believes that there may be qualitative or quantitative differences in the behavior of DEA salt due to the DEA moiety, which itself may cause effects not seen with other salts.

7. The Agency will continue to require the acceptable limit of hydrazine occuring in technical products be $\leq$ 15ppm as required by the PD-4.

Rationale: The RPAR review, now called special review, indicated that hydrazine is oncogenic and determined that the potential risk associated with this level is very low.

8. The Agency has determined that product chemistry data for all technical and MPs of MH must be submitted and updated. Refer to charts for details.

Rationale: It is Agency policy to require that all product chemistry data for technical and MPs be updated for each pesticide.

9. The Agency has determined that all end use products containing the DEA salt of MH must be tested for nitrosamines if and when the manufacturers comply with data requirements that resulted in suspension.

Rationale: Available data indicate that nitrosamines may occur in products containing the DEA salt of MH and that some nitrosamines are known carcinogens.

10. The Agency has determined that reentry data or restrictions are not required for MH at this time.

Rationale: Current use patterns of MH (7- to 70-day PHI) or application to plants at early growth stages indicate little likelihood of exposure or low exposure to workers reentering the field. The placement of MH in Toxicity Category IV for acute dermal and acute oral toxicity indicates minimal risk to humans.

11. The Agency will not require labeling to protect endangered species at this time for products containing MH.

Rationale: Acute toxicity data on mammals, avian species, and aquatic species coupled with low potential for exposure to MH indicate that endangered species are not expected to be adversely affected by the use of MH. Since MH is a plant growth retardant, it could affect any endangered plant species occurring in areas where MH is applied to tobacco cropland, citrus, apples, onions, and potatoes. However, no endangered plant species are listed as occurring at these sites. Refer to Part III.F. for detailed information.

12. The Agency has determined that Tier I nontarget area phototoxicity testing will be required for MH.

Rationale: No data are available on phytotoxicity of MH to plants. Because MH is a plant growth retardant, there are possible effects to nontarget plants; therefore, the data are required.

13. The Agency will not require additional residue data on cranberries.

Rationale: The available residue data support the established tolerances on cranberries.

14. The Agency will require additional residue data on potatoes, onions, tobacco, nonbearing citrus, and nonbearing apples. Refer to charts for detailed information on required testing.

Rationale: Available data are not sufficient to support the established tolerances for potatoes and onions. Available data are not sufficient to support the nonfood classification of nonbearing citrus and nonbearing apples. The available data on tobacco are not sufficient to adequately assess the exposure of man to residues of MH occurring in tobacco.

15. The Agency is requiring additional livestock and plant metabolism data, and storage stability data on all residue data previously submitted and any new residue data requested by this document.

Rationale: The available plant metabolism data are not adequate to fulfill requirements. There are no livestock metabolism or storage stability data available for MH.

16. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency, for the reasons stated.

Part 158
Subpart C- Product Chemistry; Concern about hazard presented by impurities

61-2 - Description of beginning materials and manufacturing process

61-3 - Preliminary analysis of product samples (hydrazine and nitrosamine data)

§158.240 - Residue Chemistry

171-4 - Plant metabolism because data required for individual commodities are dependent on this data.

171-4 - Animal metabolism to determine if tolerance on minor commodities are needed.

171-4 - Pryolysis residue data for tobacco to determine if subchronic inhalation studies are needed.

§158.290 - Environmental Fate to fully define the potential of MH to contaminate groundwater.

161-3 - Photodegradation in soil

161-1 - Aerobic soil metabolism

161-2 - Anaerobic soil metabolism

§158.340 - Toxicology to fully determine toxicological potential of MH.

81-6 - Dermal sensitization

81-3 - Chronic toxicity in rodents and nonrodents

83-2 - Oncogenicity study in rats

83-3 - Teratology study in rats

84-2 - Mutagenicity testing

85-1 - General metabolism

§158.540 - Plant Protection - Tiered Studies

122-1 - Tier I - Seed Germination/seedling emergence

122-1 - Tier I - Vegative vigor

17. While data gaps are being filled, currently registered MPs and EPs containing MH must be formulated and used, subject to the terms and conditions in the data appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or are inadequate. See FIFRA sections 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain MH or its K or DEA salts, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, MPs must contain MH, its K salt, or its DEA salt. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products as well as impurities found at > 0.1 percent. Technical MH used in formulating products must not contain hydrazine greater than 15 ppm.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and MPs containing MH and salt provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, MPs may be labeled for formulation into EPs registered for the uses listed in Appendix B, EPA Index to Pesticide Chemicals -- Maleic Hydrazide. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

D. Required Labeling

All products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2, 83-3, and below.

No pesticide product containing maleic Hydrazide or its salts ingredient may be released for shipment by the registrant after June 30, 1989, unless the product bears an amended label which complies with the requirements of this standard. Five (5) copies of the labeling, revised in accordance with this Standard, must be submitted prior to release for shipment.

Pesticide products containing maleic hydrazide or its salts ingredient may not be distributed, sold, offered for sale, (having been so received) delivered or offered to be delivered by any person after July 30, 1990 unless the product bears amended labeling, five copies of which have been submitted to the Agency, that complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredients:

Maleic hydrazide
1,2-dihydro-3,6-pyridazinedione

2. Precautionary Statements

Statements for MPs:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in the NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewer treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Statements for EPs:

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

3. The following statements must appear on all EPs:

"Wear a long-sleeve shirt, long pants, and chemical resistant gloves at all times when mixing, loading, handling, or applying this chemical."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

2. If eligible for the formulator's exemption, the data requirements listed in Table B-2

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide

EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other

registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table B-2. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months of receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

Within 9 months from the receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

Applications for full Federal registration of intrastate products are required to be submitted no later than July 31, 1988.

F. Addresses

The required information must be submitted to the following address:

Robert Taylor
Product Manager (PM) 25
Fungicide Herbicide Branch
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, B, and B-2 contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table B-2 contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? 9/	Bibliographic Citation 9/	Must Additional Data be Submitted?	Timeframe For Data Submission
Part 158					
Subpart C - Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes1/	6 months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes2/	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes3/	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes4/	6 months
63-3 - Physical State	TGAI	No	N/A	Yes4/	6 months
63-4 - Odor	TGAI	No	N/A	Yes4/	6 months
63-5 - Melting Point	TGAI	No	N/A	Yes4/,5/	6 months
63-6 - Boiling Point	TGAI	No	N/A	NO4/,6/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement Part 158	Test Substance	Does EPA Have Data To Satisfy These Requirements?[9]	Bibliographic Citation[9]	Must Additional Data be Submitted?	Timeframe For Data Submission
Subpart C - Product Chemistry (Continued)					
Physical and Chemical Characteristics (cont'd)					
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	N/A	Yes[4]	6 months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[4]	6 months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[4]	6 months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[4]	6 months
63-11 - Octanol/Water Partition Coefficient	PAI	No	N/A	Yes[4],[7]	6 months
63-12 - pH	TGAI	No	N/A	Yes[4],[8]	6 months
63-13 - Stability	TGAI	No	N/A	Yes[4]	6 months
Other Requirement:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Part 158

Subpart C - Product Chemistry (Continued)

1/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

2/ A detailed discussion must be submitted of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.

3/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Specific analyses for the potential impurity, hydrazine, must be included. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

4/ Physicochemical characteristics must be submitted (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{ow}, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D.

5/ Data needed because technical chemical is a solid at room temperature.

6/ Data not required because technical chemical is not a liquid at room temperature.

7/ Required because the technical chemical is organic and nonpolar.

8/ Required if the test substance is dispersible with water.

9/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission[1/]
§158.240 Residue Chemistry					
171-2 - Chemical Identity[2/]					
171-3 - Directions for Use		(See Index)			
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Partially	00106979,00121599 00122399,00125641	Yes[3/]	18 months
- Livestock	PAIRA and Plant Metabolites	No	N/A	Yes[4/],[5/]	18 months
171-4 - Residue Analytical Methods	TGAI and Metabolites	Partially	00058579,00087400 00100749,00101295 00106267,00106979 00106983,00112750 00122366,00125636	Yes[6/],[7/]	15 months
171-4 - Storage Stability	TEP and Metabolites	Partially	00058587	Yes[8/]	18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission 1/
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Root and Tuber Vegetables					
o Potatoes	TEP	Partially	00086764,00106979 00121603,00122361 00122364	Yes 9/ Yes 10/	18 months 24 months
- Bulb Vegetables					
o Onions	TEP	Partially	00058587,00106979 00121605,00122363 00141353	Yes 11/	18 months
- Small Fruits and Berries					
o Cranberries	TEP	Yes	00100749,00101298	No	
- Nonbearing Orchard Crops					
o Apples	TEP	No	N/A	Yes 12/	18 months
o Citrus Fruits	TEP	Partially	00101296	Yes 13/	18 months
- Tobacco	TEP PAIRA	Partially	00087392,00125636 00165460	Yes 14/ Yes 15/	18 months 24 months
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00106979	Yes 16/	18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes

1/ Data must be submitted within the indicated timeframe, based on the issue date of this Guidance Document.

2/ The same chemical identity data are required as under Part 158 Subpart C- Product Chemistry, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

3/ Studies must be submitted depicting the distribution and the metabolism of [ring-^{14}C]maleic hydrazide (acid) in cranberries, onions, and potatoes and [ethyl-^{14}C]diethanolamine salt of maleic hydrazide in onions and potatoes following foliar broadcast applications at rates sufficiently high to permit complete characterization of all ^{14}C-residues. These studies must include specific protocols to characterize and quantify the impurity hydrazine. Analyses must include hydrolysis and reextraction of plant samples and aqueous fractions to determine conjugated ^{14}C-residues of maleic hydrazide. Representative samples from these studies must also be analyzed using all current and proposed enforcement methods (including all FDA Multiresidue Protocols [I-IV], Method I in PAM Vol. II and the modification of Lane [MRID No. 00106983]) to ascertain that these methods are capable of adequately recovering and quantifying all residues of concern.

4/ Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with [ring-^{14}C]maleic hydrazide (acid) at a level high enough to permit identification and quantification of the ^{14}C-residues. These studies must also include specific protocols to characterize and quantify the impurity hydrazine. If necessary, hydrolysis and reextraction of samples and aqueous fractions must be used to release ^{14}C-conjugates. Milk and eggs must be collected within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using all current and proposed enforcement methods (including all FDA Multiresidue Protocols [I-IV], and Method I in PAM Vol. II) to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. [If the required plant metabolism studies using the [ethyl-^{14}C]diethanolamine salt of maleic hydrazide reveal that diethanolamine per se and/or the diethanolamine salt will occur as a residue in or on potatoes, metabolism studies in ruminants and poultry are also required using [^{14}C]diethanolamine and/or the [ethyl-^{14}C]diethanolamine salt.]

5/ Data depicting the nature of maleic hydrazide residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of maleic hydrazide in these animals differs from that in rats.

6/ We have required that Multiresidue Methods I-IV, Method I in PAM Vol. II, and the modification of Lane (MRID No. 00106983) be tested in conjunction with the required plant and animal metabolism studies. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB 203734/AS.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes (cont'd)

7/ If the required animal metabolism data reveal metabolites, analytical methods for data collection and tolerance enforcement will be required.

8/ Samples bearing measurable field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and stored under conditions and for intervals equivalent to those under and for which samples in the following previously submitted studies were stored: potatoes (MRID Nos. 00086764 and 00121603), onions (00121605), and cranberries (00100749 and 00101298). Also, all residue data requested in this Standard must be accompanied by sample storage data (storage conditions and time stored) and data depicting the stability of residues under the conditions and for the time intervals specified.

9/ Data must be submitted depicting maleic hydrazide residues in or on potatoes following treatment with EC and SC/L diethanolamine salt formulations and EC potassium salt formulations at 3 lb ai/A. Each salt and formulation class must be reflected in a separate test. Application must be made to uniformly flowering potatoes 7 days following blossom drop and to irrigated potatoes 2 to 3 weeks following full bloom when tubers are 1 inch in diameter. Tests must be conducted in CA (6%), ID (25%), ME (7%), MI (4%)/WI (6%), and OR (7%)/WA (15%) since these States collectively produced ca. 70% of the 1985 U.S. potato crop (Agricultural Statistics 1986, p. 164). A PHI must be proposed and reflected in the submitted data. The registrant must also propose a PHI for the potassium salt SC/L and SC/S labels and amend the labels to permit only a single application/year.

10/ Data must be submitted depicting maleic hydrazide residues in chips, granules, and wet and dry peel, processed from potatoes bearing measurable weathered residues. If residues concentrate in peel or granules, appropriate feed/food additive tolerances must be proposed. The established food additive tolerance for chips will be reassessed following evaluation of these data.

11/ Data must be submitted depicting maleic hydrazide residue in or on dry bulb onions following application of a diethanolamine salt of an EC and SC/L formulation and potassium salt of an EC formulation, in separate tests, at 2 pounds acid equivalent per acre (lb ae/A). Tests must be conducted in CA (27%), CO (12%), ID (8%), MI (6%), NY (9%), OR (15%)/ WA (5%), and TX (9%) since these States collectively produced ca. 74% of the 1985 U.S. storage onion crop (Agricultural Statistics 1986, p. 161). A PHI must be proposed and reflected in the submitted data. The registrant must also propose a PHI for the potassium salt SC/S and SC/L labels and amend the labels to permit a single application/year.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes (cont'd)

12/ Data must be submitted depicting maleic hydrazide residues in or on apples treated with the 3 lb/gal SC/L diethanolamine salt formulation at 6 lb ae/A in a nonbearing year. Fruit must be harvested at the shortest possible interval following registered use and should include tests using early maturing varieties. Tests must be conducted in CA (8%), MI (14%), NY (14%)/PA (7%), and WA (26%) because these States produced ca. 70% of the 1985 U.S. apple crop (Agricultural Statistics 1986, p. 186). Upon receipt of the requsted data, the appropriateness of the nonfood use classication will be assessed. If residues are detectable in or on fruit, a tolerance must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products (wet and dry pomace and juice).

13/ Data must be submitted depicting maleic hydrazide residues in or on citrus fruits (oranges and grapefruit) treated twice (November 15 and 8 weeks later) to runoff with the EC and SC/L potassium and diethanolamin salt formulations, in separate tests, at 1.5 lb ae/100 gal water in a nonbearing year. Fruit must be harvested at the shortest possible interval following registered use and should include tests using early maturing varieties. Tests must be conducted in Florida. The registrant must propose a maximum rate or volume/A, which must be reflected in the submitted data. Upon receipt of the requested data, the appropriateness of the nonfood use classification will be assessed. If residues are detectable in or on fruit, a tolerance must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products (dried pulp, oil, molasses, juice).

14/ Data must be submitted depicting maleic hydrazide residues in or on green freshly harvested and cured or dry tobacco leaves following foliar broadcast application (i) after topping to plants in full flower with the EC and SC/L diethanolamine formulation (in separate tests) at 3 lb ae/A; and (ii) 7 days prior to harvest using an SC/L potassium salt formulation at 4.5 lb ae/A to dark-fired tobacco varieties. The residues data must include decline decline studies at regular intervals following application of diethanolamine salts to tobacco. Tests must be conducted in KY (28%), NC (37%), and TN (8%), States which produced ca. 73% of the 1985 U.S. tobacco crop (Agricultural Statistics 1986, p. 93).

15/ Pyrolysis products derived from the active ingredient must be characterized and the level of the residue in smoke must be quantified. ([^{14}C]maleic hydrazide must be used for identification of pyrolysis products.)

16/ Following receipt and evaluation of the required plant and animal metabolism data and residue data for potatoes (feed items = cull potatoes and processed potato waste), specific data requirements for livestock feeding studies will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	TGAI	Yes	00079657	No	
81-2 - Acute Dermal - Rabbit	TGAI	Yes	00079658	No	
81-3 - Acute Inhalation - Rat	TGAI	No		Yes	9 months
81-4 - Eye Irritation - Rabbit	TGAI	Yes	00079661	No	
81-5 - Dermal Irritation - Rabbit	TGAI	Yes	00079660	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	No		Yes	9 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	No		No[1]	
SUBCHRONIC TESTING					
82-1-90-Day Feeding-					
Rodent	TGAI	No		No [2]	
Non-Rodent	TGAI	No		No [2]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
SUBCHRONIC TESTING: (cont'd)					
82-2 - 21-Day Dermal	TGAI	No		Yes	15 months
82-3 - 90-Day Dermal	TGAI	No		No3/	
82-4 - 90-Day Inhalation	TGAI	No		Reserved4/	
82-5 - 90-Day Neurotoxicity	TGAI	No		No1/	
CHRONIC TESTING:					
83-1 - Chronic Toxicity					
- Rodent	TGAI	No		Yes	50 months
- Nonrodent	TGAI	No		Yes	50 months
83-2 - Oncogenicity Study				Yes	50 months
- Rat	TGAI	No			
- Mouse	TGAI	Yes	00098466 40663501	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
CHRONIC TESTING: (cont'd)					
83-3 - Teratogenicity					
- Rat	TGAI	No		Yes	12 months
- Rabbit	TGAI	Partially	00128721	Yes[5]	12 months
83-4 - Reproduction	TGAI	Yes	00128720	No	
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	Yes	00124883	No	
84-2 - Chromosomal Aberration	TGAI	No		Yes	12 months
84-2 - Other Mechanisms of Mutagenicity	TGAI	No		Yes	12 months
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	No		Yes	24 months
85-2 - Domestic Animal Safety	Choice	No		Yes	24 months

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.340 Toxicology Footnotes

1/ Not required because maleic hydrazide is not an organophosate.

2/ This data requirement is waived based on the requirement for chronic studies in rodent and nonrodent.

3/ Uses do not involve purposeful, prolonged, or comparable dermal exposure.

4/ Repeated inhalation exposures at toxic concentrations are not expected; however, because of tobacco use, an inhalation study may be required for maleic hydrazide and pyrolysis products depending upon their presence in and nature on tobacco.

5/ Addition data required on parentage of affected offspring.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission 1/
§158.290 Environmental Fate						
Product Identity and Composition						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	PAIRA	A,B	Yes	00143322	No	
Photodegradation						
161-2 - In Water	PAIRA	A,B	Partially	00151951	Yes2/	9 months
161-3 - On Soil	PAIRA	A,B	Yes	00151951	No	
161-4 - In Air	PAIRA	A,B	No	-	Reserved3/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	PAIRA	A,B	No	-	Yes	27 months
162-2 - Anaerobic Soil	PAIRA	A,B	No	-	Yes	27 months
162-3 - Anaerobic Aquatic	PAIRA	-	No	-	No4/	
162-4 - Aerobic Aquatic	PAIRA	-	No	-	No5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.290 Environmental Fate (cont'd)						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	PAIRA	A,B	Partially	00151952	Yes6/	12 months
163-2 - Volatility (Lab)	TEP	A,B	No	-	Reserved7/	
163-3 - Volatility (Field)	TEP	A,B	No	-	Reserved8/	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 months
164-2 - Aquatic (Sediment)	TEP	-	No	-	No5/	
164-3 - Forestry	TEP	-	No	-	No9/	
164-4 - Combination and Tank Mixes		-	No		No10/	
164-5 - Soil, Long-Term	TEP	-	No	-	Reserved11/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.290 Environmental Fate (cont'd)						
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,B	Partially	00122390	Yes 12/	39 months
165-2 - Rotational Crops (Field)	TEP	A,B	No	-	Reserved 13/	
165-3 - Irrigated Crops	TEP	-	No	-	No 5/	
165-4 - In Fish	PAIRA/TGAI	A,B	Yes	00163301	No 14/	
165-5 - In Aquatic Nontarget Organisms	TEP	-	No	-	No 4/	
§158.142 Spray Drift						
202-1 - Drift Field Evaluation	TEP	A,B	No	-	No 15/	
202-1 - Droplet Size Spectrum	TEP	A,B	No	-	No 15/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.290 Environmental Fate Footnotes

1/ Data must be submitted within the indicated timeframes, based on the issue date of this guidance document.

2/ An absorption spectrum of maleic hydrazide is required.

3/ The requirement for data is reserved pending the results of an acceptable acute inhalation study.

4/ This study is not required to support the current use pattern, which does not include aquatic, forestry, or aquatic impact uses.

5/ This study is not required to support the current use pattern, which does not include aquatic or aquatic impact uses.

6/ This study is partially acceptable: An unaged adsorption/desorption study using five soils was acceptable; however, an aged soil column study using two soils (one sand plus one representative of intended use area) is required.

7/ The requirement for the study is reserved pending results of an acceptable acute inhalation study.

8/ The requirement for the study is reserved pending the results of the laboratory volatility study.

9/ This study is not required because the current use pattern does not include forestry uses.

10/ There are no current registered combination or tank mixes for maleic hydrazide.

11/ The requirement for this study is reserved pending the results of the field dissipation study (§164-1).

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission1/
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Root and Tuber Vegetables					
o Potatoes	TEP	Partially	00086764,00106979 00121603,00122361 00122364	Yes9/ Yes10/	18 months 24 months
- Bulb Vegetables					
o Onions	TEP	Partially	00058587,00106979 00121605,00122363 00141353	Yes11/	18 months
- Small Fruits and Berries					
o Cranberries	TEP	Yes	00100749,00101298	No	
- Nonbearing Orchard Crops					
o Apples	TEP	No	N/A	Yes12/	18 months
o Citrus Fruits	TEP	Partially	00101296	Yes13/	18 months
- Tobacco	TEP PAIRA	Partially	00087392,00125636 00165460	Yes14/ Yes15/	18 months 24 months
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00106979	Yes16/	18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes

1/ Data must be submitted within the indicated timeframe, based on the issue date of this Guidance Document.

2/ The same chemical identity data are required as under Part 158 Subpart C- Product Chemistry, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

3/ Studies must be submitted depicting the distribution and the metabolism of [ring-^{14}C]maleic hydrazide (acid) in cranberries, onions, and potatoes and [ethyl-^{14}C]diethanolamine salt of maleic hydrazide in onions and potatoes following foliar broadcast applications at rates sufficiently high to permit complete characterization of all ^{14}C-residues. These studies must include specific protocols to characterize and quantify the impurity hydrazine. Analyses must include hydrolysis and reextraction of plant samples and aqueous fractions to determine conjugated ^{14}C-residues of maleic hydrazide. Representative samples from these studies must also be analyzed using all current and proposed enforcement methods (including all FDA Multiresidue Protocols [I-IV], Method I in PAM Vol. II and the modification of Lane [MRID No. 00106983]) to ascertain that these methods are capable of adequately recovering and quantifying all residues of concern.

4/ Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with [ring-^{14}C]maleic hydrazide (acid) at a level high enough to permit identification and quantification of the ^{14}C-residues. These studies must also include specific protocols to characterize and quantify the impurity hydrazine. If necessary, hydrolysis and reextraction of samples and aqueous fractions must be used to release ^{14}C-conjugates. Milk and eggs must be collected within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using all current and proposed enforcement methods (including all FDA Multiresidue Protocols [I-IV], and Method I in PAM Vol. II) to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. [If the required plant metabolism studies using the [ethyl-^{14}C]diethanolamine salt of maleic hydrazide reveal that diethanolamine per se and/or the diethanolamine salt will occur as a residue in or on potatoes, metabolism studies in ruminants and poultry are also required using [^{14}C]diethanolamine and/or the [ethyl-^{14}C]diethanolamine salt.]

5/ Data depicting the nature of maleic hydrazide residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of maleic hydrazide in these animals differs from that in rats.

6/ We have required that Multiresidue Methods I-IV, Method I in PAM Vol. II, and the modification of Lane (MRID No. 00106983) be tested in conjunction with the required plant and animal metabolism studies. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB 203734/AS.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes (cont'd)

7/ If the required animal metabolism data reveal metabolites, analytical methods for data collection and tolerance enforcement will be required.

8/ Samples bearing measurable field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and stored under conditions and for intervals equivalent to those under and for which samples in the following previously submitted studies were stored: potatoes (MRID Nos. 00086764 and 00121603), onions (00121605), and cranberries (00100749 and 00101298). Also, all residue data requested in this Standard must be accompanied by sample storage data (storage conditions and time stored) and data depicting the stability of residues under the conditions and for the time intervals specified.

9/ Data must be submitted depicting maleic hydrazide residues in or on potatoes following treatment with EC and SC/L diethanolamine salt formulations and EC potassium salt formulations at 3 lb ai/A. Each salt and formulation class must be reflected in a separate test. Application must be made to uniformly flowering potatoes 7 days following blossom drop and to irrigated potatoes 2 to 3 weeks following full bloom when tubers are 1 inch in diameter. Tests must be conducted in CA (6%), ID (25%), ME (7%), MI (4%)/WI (6%), and OR (7%)/WA (15%) since these States collectively produced ca. 70% of the 1985 U.S. potato crop (Agricultural Statistics 1986, p. 164). A PHI must be proposed and reflected in the submitted data. The registrant must also propose a PHI for the potassium salt SC/L and SC/S labels and amend the labels to permit only a single application/year.

10/ Data must be submitted depicting maleic hydrazide residues in chips, granules, and wet and dry peel, processed from potatoes bearing measurable weathered residues. If residues concentrate in peel or granules, appropriate feed/food additive tolerances must be proposed. The established food additive tolerance for chips will be reassessed following evaluation of these data.

11/ Data must be submitted depicting maleic hydrazide residue in or on dry bulb onions following application of a diethanolamine salt of an EC and SC/L formulation and potassium salt of an EC formulation, in separate tests, at 2 pounds acid equivalent per acre (lb ae/A). Tests must be conducted in CA (27%), CO (12%), ID (8%), MI (6%), NY (9%), OR (15%)/ WA (5%), and TX (9%) since these States collectively produced ca. 74% of the 1985 U.S. storage onion crop (Agricultural Statistics 1986, p. 161). A PHI must be proposed and reflected in the submitted data. The registrant must also propose a PHI for the potassium salt SC/S and SC/L labels and amend the labels to permit a single application/year.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.240 Residue Chemistry Footnotes (cont'd)

12/ Data must be submitted depicting maleic hydrazide residues in or on apples treated with the 3 lb/gal SC/L diethanolamine salt formulation at 6 lb ae/A in a nonbearing year. Fruit must be harvested at the shortest possible interval following registered use and should include tests using early maturing varieties. Tests must be conducted in CA (8%), MI (14%), NY (14%)/PA (7%), and WA (26%) because these States produced ca. 70% of the 1985 U.S. apple crop (Agricultural Statistics 1986, p. 186). Upon receipt of the requsted data, the appropriateness of the nonfood use classication will be assessed. If residues are detectable in or on fruit, a tolerance must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products (wet and dry pomace and juice).

13/ Data must be submitted depicting maleic hydrazide residues in or on citrus fruits (oranges and grapefruit) treated twice (November 15 and 8 weeks later) to runoff with the EC and SC/L potassium and diethanolamin salt formulations, in separate tests, at 1.5 lb ae/100 gal water in a nonbearing year. Fruit must be harvested at the shortest possible interval following registered use and should include tests using early maturing varieties. Tests must be conducted in Florida. The registrant must propose a maximum rate or volume/A, which must be reflected in the submitted data. Upon receipt of the requested data, the appropriateness of the nonfood use classification will be assessed. If residues are detectable in or on fruit, a tolerance must be proposed and a processing study conducted to assess potential concentration of residues in food and feed products (dried pulp, oil, molasses, juice).

14/ Data must be submitted depicting maleic hydrazide residues in or on green freshly harvested and cured or dry tobacco leaves following foliar broadcast application (i) after topping to plants in full flower with the EC and SC/L diethanolamine formulation (in separate tests) at 3 lb ae/A; and (ii) 7 days prior to harvest using an SC/L potassium salt formulation at 4.5 lb ae/A to dark-fired tobacco varieties. The residues data must include decline decline studies at regular intervals following application of diethanolamine salts to tobacco. Tests must be conducted in KY (28%), NC (37%), and TN (8%), States which produced ca. 73% of the 1985 U.S. tobacco crop (Agricultural Statistics 1986, p. 93).

15/ Pyrolysis products derived from the active ingredient must be characterized and the level of the residue in smoke must be quantified. ([^{14}C]maleic hydrazide must be used for identification of pyrolysis products.)

16/ Following receipt and evaluation of the required plant and animal metabolism data and residue data for potatoes (feed items = cull potatoes and processed potato waste), specific data requirements for livestock feeding studies will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	TGAI	Yes	00079657	No	
81-2 - Acute Dermal - Rabbit	TGAI	Yes	00079658	No	
81-3 - Acute Inhalation - Rat	TGAI	No		Yes	9 months
81-4 - Eye Irritation - Rabbit	TGAI	Yes	00079661	No	
81-5 - Dermal Irritation - Rabbit	TGAI	Yes	00079660	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	No		Yes	9 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	No		No[1]	
SUBCHRONIC TESTING					
82-1-90-Day Feeding-					
Rodent	TGAI	No		No [2]	
Non-Rodent	TGAI	No		No [2]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
SUBCHRONIC TESTING: (cont'd)					
82-2 - 21-Day Dermal	TGAI	No		Yes	15 months
82-3 - 90-Day Dermal	TGAI	No		No3/	
82-4 - 90-Day Inhalation	TGAI	No		Reserved4/	
82-5 - 90-Day Neurotoxicity	TGAI	No		No1/	
CHRONIC TESTING:					
83-1 - Chronic Toxicity					
- Rodent	TGAI	No		Yes	50 months
- Nonrodent	TGAI	No		Yes	50 months
83-2 - Oncogenicity Study				Yes	50 months
- Rat	TGAI	No			
- Mouse	TGAI	Yes	00098466 40663501	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
CHRONIC TESTING: (cont'd)					
83-3 - Teratogenicity					
- Rat	TGAI	No		Yes	12 months
- Rabbit	TGAI	Partially	00128721	Yes5/	12 months
83-4 - Reproduction	TGAI	Yes	00128720	No	
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	Yes	00124883	No	
84-2 - Chromosomal Aberration	TGAI	No		Yes	12 months
84-2 - Other Mechanisms of Mutagenicity	TGAI	No		Yes	12 months
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	No		Yes	24 months
85-2 - Domestic Animal Safety	Choice	No		Yes	24 months

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.340 Toxicology Footnotes

1/ Not required because maleic hydrazide is not an organophosate.

2/ This data requirement is waived based on the requirement for chronic studies in rodent and nonrodent.

3/ Uses do not involve purposeful, prolonged, or comparable dermal exposure.

4/ Repeated inhalation exposures at toxic concentrations are not expected; however, because of tobacco use, an inhalation study may be required for maleic hydrazide and pyrolysis products depending upon their presence in and nature on tobacco.

5/ Addition data required on parentage of affected offspring.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission 1/
§158.290 Environmental Fate						
Product Identity and Composition						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	PAIRA	A,B	Yes	00143322	No	
Photodegradation						
161-2 - In Water	PAIRA	A,B	Partially	00151951	Yes2/	9 months
161-3 - On Soil	PAIRA	A,B	Yes	00151951	No	
161-4 - In Air	PAIRA	A,B	No	-	Reserved3/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	PAIRA	A,B	No	-	Yes	27 months
162-2 - Anaerobic Soil	PAIRA	A,B	No	-	Yes	27 months
162-3 - Anaerobic Aquatic	PAIRA	-	No	-	No4/	
162-4 - Aerobic Aquatic	PAIRA	-	No	-	No5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.290 Environmental Fate (cont'd)						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	PAIRA	A,B	Partially	00151952	Yes 6/	12 months
163-2 - Volatility (Lab)	TEP	A,B	No	-	Reserved 7/	
163-3 - Volatility (Field)	TEP	A,B	No	-	Reserved 8/	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 months
164-2 - Aquatic (Sediment)	TEP	-	No	-	No 5/	
164-3 - Forestry	TEP	-	No	-	No 9/	
164-4 - Combination and Tank Mixes		-	No		No 10/	
164-5 - Soil, Long-Term	TEP	-	No	-	Reserved 11/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.290 Environmental Fate (cont'd)						
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,B	Partially	00122390	Yes12/	39 months
165-2 - Rotational Crops (Field)	TEP	A,B	No	-	Reserved 13/	
165-3 - Irrigated Crops	TEP	-	No	-	No5/	
165-4 - In Fish	PAIRA/TGAI	A,B	Yes	00163301	No 14/	
165-5 - In Aquatic Nontarget Organisms	TEP	-	No	-	No4/	
§158.142 Spray Drift						
202-1 - Drift Field Evaluation	TEP	A,B	No	-	No 15/	
202-1 - Droplet Size Spectrum	TEP	A,B	No	-	No 15/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.290 Environmental Fate Footnotes

1/ Data must be submitted within the indicated timeframes, based on the issue date of this guidance document.

2/ An absorption spectrum of maleic hydrazide is required.

3/ The requirement for data is reserved pending the results of an acceptable acute inhalation study.

4/ This study is not required to support the current use pattern, which does not include aquatic, forestry, or aquatic impact uses.

5/ This study is not required to support the current use pattern, which does not include aquatic or aquatic impact uses.

6/ This study is partially acceptable: An unaged adsorption/desorption study using five soils was acceptable; however, an aged soil column study using two soils (one sand plus one representative of intended use area) is required.

7/ The requirement for the study is reserved pending results of an acceptable acute inhalation study.

8/ The requirement for the study is reserved pending the results of the laboratory volatility study.

9/ This study is not required because the current use pattern does not include forestry uses.

10/ There are no current registered combination or tank mixes for maleic hydrazide.

11/ The requirement for this study is reserved pending the results of the field dissipation study (§164-1).

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

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§158.290 Environmental Fate Footnotes (cont'd)

12/ The available study fulfills the requirement for leafy vegetables and root crops, a confined study is needed for wheat or another small grain.

13/ The requirement is reserved pending results rotational interval of the confined study or wheat.

14/ This study is not required because the reviewed octanol/water partition coefficient study (Cable, 00163301) gave a value of < 0.6, thereby indicating a very low potential for maleic hydrazide to bioaccumulate in fish.

15/ The requirement for this study is reserved pending results of an acceptable acute inhalation study.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No	-	No[1]	
132-1 - Soil Dissipation	TEP	A,B	No	-	No[1]	
133-3 - Dermal Exposure	TEP	A,B	No	-	No[1]	
133-4 - Inhalation Exposure	TEP	A,B	No	-	No[1]	

1/ Reentry data are not required because of little likelihood of exposure, or very low exposure, based on current use pattern.

TABLE A
MALEIC HYDRAZIDE GENERIC DATA REQUIREMENTS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.490 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Single-Dose Oral LD_{50}	TGAI	A,B,H	Yes	000124742	No	
	PS	A,B,H	Yes	000146141	No	
	DS	A,B,H	No		No 1/	
71-2 - Avian Dietary LC_{50}						
A. Upland Game Bird	TGAI	A,B,H	Yes	000126033	No	
	PS	A,B,H	No		No 2/	
	DS	A,B,H	No		No 1/	
B. Waterfowl	TGAI	A,B,H	Yes	000107417	No	
	PS	A,B,H	Yes	000147000	No	
	DS	A,B,H	No		No 1/	
71-2 - Avian Reproduction						
A. Upland Game Bird	TGAI,PS,DS	A,B,H	No		No	
B. Waterfowl	TGAI,PS,DS	A,B,H	No		No	
71-5 - Simulated and Actual Field Testing for Mammals and Birds	TEP,PS,DS	A,B,H	No		No	

TABLE A
MALEIC HYDRAZIDE GENERIC DATA REQUIREMENTS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.490 Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}						
A. Warmwater	TGAI	A,B,H	Yes	00124739	No	
	PS	A,B,H	No		No 2/	
	DS	A,B,H	No		No 1/	
B. Coldwater	TGAI	A,B,H	Yes	00124740	No	
	PS	A,B,H	Yes	00146142	No	
	DS	A,B,H	No		No 1/	
72-2 - Acute LC_{50} Aquatic Invertebrates	TGAI	A,B,H	Yes	00124741	No	
	PS	A,B,H	Yes		No	
	DS	A,B,H	No		No 1/	
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI,PS,DS	A,B,H	No		No 3/	
72-4 - Fish and Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI,PS,DS	A,B,H	No		No 3/	

TABLE A
MALEIC HYDRAZIDE GENERIC DATA REQUIREMENTS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.490 Wildlife and Aquatic Organisms						
AQUATIC ORGANISM TESTING (cont'd)						
72-5 - Fish Life Cycle	TGAI,PS,DS	A,B,H	No		No 3/	
72-6 - Aquatic Organism Accumulation	TGAI,PS,DS	A,B,H	No		No 3/	
72-7 - Simulated or Actual Field Testing for Aquatic Organisms	TGAI,PS,DS	A,B,H	No		No 3/	

1/ No data requirements based on the low toxicity of maleic hydrazide and the potassium salt.

2/ No data requirements based on the low toxicity of maelic hydrazide and the present data base already accumulated for the potassium salt of maleic hydrazide.

3/ Does not require any aquatic testing.

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TGAI,PS,DS	A,B,H	No		No 1/	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/	TGAI,PS,DS	A,B,H	No		Yes 2/	9 months
Seedling Emergence			No		No 1/	
122-1 - Vegetative Vigor	TGAI,PS,DS	A,B,H A,B,H	No No		Yes 2/ No 1/	9 months
122-2 - Aquatic Plant Growth	TGAI,PS,DS	A,B,H A,B,H	No No		Yes 2/ No 1/	9 months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI,PS,DS	A,B,H	No		No 3/	
123-1 - Vegetatative Vigor	TGAI,PS,DS	A,B,H	No		No 3/	
123-2 - Aquatic Plant Growth	TGAI, PS,DS	A,B,H	No		No 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.540 Plant Protection (cont'd)						
TIER III						
124-1 - Terrestrial Field	TGAI,PS,DS	A,B,H	No		No 4/	
124-2 - Aquatic Field	TGAI,PS,DS	A,B,H	No		No 4/	

1/ No data required for Diethanolamine salt based on the low toxicity of maleic hydrazide and the potassium salt.

2/ Required because the chemical is a growth retardant to plants and no phytotoxicity are available.

3/ Depending on results of Tier I testing.

4/ Tier III will depend on results of Tier II testing.

TABLE A-2
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE DIETHANOLAMINE

Data Requirement Data Requirement	Test Substance 1/	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	TGAI	No		Yes	9 months
81-2 - Acute Dermal - Rabbit	TGAI	No		Yes	9 months
81-3 - Acute Inhalation - Rat	TGAI	No		Yes	9 months
81-4 - Eye Irritation - Rabbit	TGAI	No		Yes	9 months
81-5 - Dermal Irritation - Rabbit	TGAI	No		Yes	9 months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	No		Yes	9 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	No		No 2/	
SUBCHRONIC TESTING					
82-1-90-Day Feeding-					
Rodent	TGAI	No		No 7/	
Non-Rodent	TGAI	No		No 7/	

TABLE A-2
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE DIETHANOLAMINE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
SUBCHRONIC TESTING: (cont'd)					
82-2 - 21-Day Dermal	TGAI	No		Yes	15 months
82-3 - 90-Day Dermal	TGAI	No		No3/	
82-4 - 90-Day Inhalation	TGAI	No		Reserved4/	
82-5 - 90-Day Neurotoxicity	TGAI	No		No5/	
CHRONIC TESTING:					
83-1 - Chronic Toxicity					
- Rodent	TGAI	No		Yes	50 months
- Nonrodent	TGAI	No		Yes	50 months
83-2 - Oncogenicity Study					
- Rat	TGAI	No		Yes	50 months
- Mouse	TGAI	No		Yes	50 months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE DIETHANOLAMINE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy These Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.340 Toxicology					
CHRONIC TESTING: (cont'd)					
83-3 - Teratogenicity					
- Rat	TGAI	No		Yes	12 months
- Rabbit	TGAI	No		Yes	12 months
83-4 - Reproduction	TGAI	No		Yes	39 months
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	No		Yes	9 months
84-2 - Chromosomal Aberration	TGAI	No		Yes	12 months
84-2 - Other Mechanisms of Mutagenicity	TGAI	No		Yes	12 months
SPECIAL TESTING					
85-1 - General Metabolism	TGAI	No		Yes	24 months
85-2 - Domestic Animal Safety	TGAI	No		Yes 6/	24 months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR MALEIC HYDRAZIDE DIETHANOLAMINE

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§158.340 Toxicology Footnotes

1/ This testing must be done on the maleic hydrazide technical plus DEA(diethanolamine) salt.

2/ Not required because maleic hydrazide is not an organophosate.

3/ Uses do not involve purposeful, prolonged, or comparable dermal exposure.

4/ Repeated inhalation exposures at toxic concentrations are not expected; however, because of tobacco use, an inhalation study may be required for maleic hydrazide and pyrolysis products depending upon their presence in and nature on tobacco.

5/ Since an acute neurotoxicity study is not required for this compound and there is no evidence of neurotoxicity in mammalian species this study is not required.

6/ This study should place emphasis on the diethanolamine moiety.

7/ This data requirement is waived based on the requirement for chronic studies in rodent and nonrodent.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Data Requirement	Composition a/	Does EPA Have Data To Satisfy These Requirements?1/	Bibliographic Citation1/	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submissiom
Part 158 Subpart C -Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes2/	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes3/	6 months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes4/	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes5/	12 months
62-2 - Certification of Ingredient Limits	MP	No	N/A	Yes6/	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes7/	12 months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Data Requirement	Composition	Does EPA Have Data To Satisfy These Requirements?1/	Bibliographic Citation1/	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submissiom
Part 158					
Subpart C - Product Chemistry(cont'd)					
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes8/	6 months
63-3 - Physical State	MP	No	N/A	Yes8/	6 months
63-4 - Odor	MP	No	N/A	Yes8/	6 months
63-7 - Density, Bulk Density, or Specific Gravity	MP	No	N/A	Yes8/	6 months
63-12 - pH	MP	No	N/A	Yes8/,9/	6 months
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes8/,10/	6 months
63-15 - Flammability	MP	No	N/A	Yes8/,11/	6 months
63-16 - Explodability	MP	No	N/A	Yes8/,12/	6 months
63-17 - Storage Stability	MP	No	N/A	Yes8/	15 months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Data Requirement	Composition	Does EPA Have Data To Satisfy These Requirements?1/	Bibliographic Citation1/	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submissiom
Part 158 Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-18 - Viscosity	MP	No	N/A	Yes8/,13/	6 months
63-19 - Miscibility	MP	No	N/A	Yes8/,14/	6 months
63-20 - Corrosion	MP	No	N/A	Yes8/	15 months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Part 158
Subpart C - Product Chemistry footnotes

a/ Manufacturing -Use Product.

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name, nominal concentration, Chemical Abstracts Service (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/ A detailed discussion must be submitted on all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. Specific analyses for the potential impurity, hydrazine, must be included.

6/ Upper and lower limits must be submitted for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) must be provided and certified. An upper limit for the impurity hydrazine at $\leq$ 15 ppm must be included. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.).
Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 (Rev. 2-85).

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Part 158
Subpart C - Product Chemistry (cont'd)

7/ Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ Physicochemical characteristics must be submitted (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D.

9/ Required if the test substance is dispersible with water.

10/ Required if the product contains an oxidizing or reducing agent.

11/ Required if the product contains combustible liquids.

12/ Required if the product is potentially explosive.

13/ Required if the product is a liquid.

14/ Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B-2
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DEA SALTS OF MALEIC HYDRAZIDE

Data Requirement	Composition a/	Does EPA Have Data To Satisfy These Requirements?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	Any Product	No	N/A	Yes[2]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	Any Product	No	N/A	Yes[3]	6 months
61-3 - Discussion of Formation of Impurities	Any Product	No	N/A	Yes[4]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	Any Product	No	N/A	Yes[5]	12 months
62-2 - Certification of Ingredient Limits	Any Product	No	N/A	Yes[6]	12 months
62-3 - Analytical Methods to Verify Certified Limits	Any Product	No	N/A	Yes[7]	12 months

TABLE B-2
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DEA SALTS OF MALEIC HYDRAZIDE

Data Requirement Part 158	Composition	Does EPA Have Data To Satisfy These Requirements?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submissiom
Subpart C - Product Chemistry					
Physical and Chemical Characteristics					
63-2 - Color	Any Product	No	N/A	Yes[8]	6 months
63-3 - Physical State	Any Product	No	N/A	Yes[5]	6 months
63-4 - Odor	Any Product	No	N/A	Yes[5]	6 months
63-7 - Density, Bulk Density, or Specific Gravity	Any Product	No	N/A	Yes[5]	6 months
63-12 - pH	Any Product	No	N/A	Yes[5], [9]	6 months
63-14 - Oxidizing or Reducing Action	Any Product	No	N/A	Yes[8], [10]	6 months
63-15 - Flammability	Any Product	No	N/A	Yes[8], [11]	6 months
63-16 - Explodability	Any Product	No	N/A	Yes[8], [12]	6 months
63-17 - Storage Stability	Any Product	No	N/A	Yes[8]	15 months

TABLE B-2
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DEA SALTS OF MALEIC HYDRAZIDE

Part 158
Subpart C - Product Chemistry Footnotes

a/ The requirements are required for any product containing the diethanolamine salt(DEA) of maleic hydrazide.

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name, nominal concentration, Chemical Abstracts Service (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/ A detailed discussion must be submitted on all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production. Specific discussion of nitrosomine formation must be encluded regardless of quantity.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. All nitrosamines must be identified and quantified by methods sensitive to 1ppm N-Nitrose contaminants in six samples of each diethanolamine salt end-use product; two samples of each must be analyzed shortly after production, two at 3 months after production , and two at 6 months after production.

6/ Upper and lower limits must be submitted for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $\geq 0.1\%$ (w/w) and each "toxicologically significant" impurity present at $< 0.1\%$ (w/w) must be provided and certified. An upper limit for the impurity hydrazine at ≤ 15 ppm must be included. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications

TABLE B-2
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DEA SALT OF MALEIC HYDRAZIDE

Part 158

Subpart C - Product Chemistry (cont'd)

7/ Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity intentionally added inert and nitrosamines which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date ________________________________

Registration Standard for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Part 158 Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "Sec Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.56(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word,
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

#8

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

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[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Maleic Hydrazide Standard

MRID	CITATION
00058587	Uniroyal Chemical (1951) Maleic hydrazide Residue. (Unpublished study received Dec 22, 1952 under 400-38; CDL:231189-L)
00058579	Harris, W.D. (1951) Residue Determinations of Maleic hydrazide in Milk and Grass. (Unpublished study received Apr 4, 1952 under 400-38; submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 231189-D)
00079657	Shapiro, R. (1977) Acute Oral Toxicity: Report No. T-235. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-G)
00079658	Shapiro, R. (1977) Acute Dermal Toxicity: Report No. T-242. (Unpublished study recieved Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-H)
00079660	Shapiro, R. (1977) Primary Skin Irritation: Report No. T-212. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-J)
00079661	Shapiro, R. (1977) Eye Irritation: Report No. T-220. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Nutrition International, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:232654-K)
00086764	Uniroyal Chemical (1981) Summary of MH Residue in Potatoes Treated with Royal MH-30. (Compilation; unpublished study received Nov 3, 1981 under 400-84; CDL:246227-A)
00087392	Guthrie, F.E.; Bowery, T.G. (1967) Pesticide residues on tobacco. Residue Review 19:31-56. (Also in unpublished submission received on unknown date under unknown admin. no.; submitted by ?; CDL:120496-E)
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MRID	CITATION
00098466	Jessup, D.C.; Trumbull, R.R.; Richter, W.R.; et al. (1981) Lifetime Oncogenicity Study in Mice: 399-007. (Unpublished study received Jan 1, 1981 under unknown admin. no.; prepared by International Research and Development Corp., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:247226-A; 247227)
00100749	Interregional Research Project No. 4 (1980) The Results of Tests on the Amount of Maleic Hydrazide Residues Remaining in or on Cranberries Including a Description of the Analytical Method Used. (Compilation; unpublished study received May 4, 1982 under 2E2676; CDL:070832-A)
00101295	United States Rubber Co. (19??) General Method G-114-A: Maleic Hydrazine (MH) Residues. (Unpublished study received on unknown date under PP0284; CDL:092562-A)
00101296	United States Rubber Co. (1960) MH Residue in Lemon Juice, in Lemon Peel and in Whole Lemon. (Unpublished study received on unknown date under PP0284; CDL:092562-B)
00101298	United States Rubber Co. (1960) [Residues of MH in Cranberries]. (Compilation; unpublished study received on unknown date under PP0284; CDL:092562-D)
00106267	Lane, J.; Gullstrom, D.; Newell, J. (1953?) Adaptation of Residue Methods To Include New Vegetables or To Extend the Sensitivity Range; Extension of the Residue Methods for Maleic Hydrazide and Alanap. (Unpublished study received May 10, 1957 under unknown admin. no.; submitted by Uniroyal Chemical, Bethany, CT; CDL:121143-A)
00106979	Naugatuck Chemical (1954) [Maleic Hydrazide: Residues in Beans and Other Crops]. (Compilation; unpublished study received on unknown date under PP0027; CDL:092309-B)
00106983	Lane, J. (1959) Maleic Hydrazide (MH) Residues: General Method G-114-A. (Unpublished study received Feb 16, 1961 under PP0284; submitted by U.S. Rubber Co., Naugatuck, CT; CDL:092563-A)
00107417	Fink, R. (1974) Final Report: Eight-day Dietary LC50—Mallard Ducks: [Technical MH]: Project No. 117-106. (Unpublished study received Aug 20, 1974 under 400-41; prepared by Truslow Farms, Inc., submitted by Uniroyal Chemical, Bethany, CT; CDL:130997-A)

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MRID	CITATION
00112750	United States Rubber Co. (1957) The Results of Tests by Practicable Methods to Determine the Amount of the Food Additive [Maleic Hydrazide] in the Finished Food and of Any Substance Formed in or on the Food Because of Its Use. (Compilation; unpublished study received May 26, 1959 under unknown admin. no.; CDL: 221555-B)
00121599	Brown, M.; Hitz, C. (1957) An interpretation of the influence of maleic hydrazide upon the growth of strawberry runners based upon radioisotope studies. Proceedings of the American Society for Horticultural Science 70:131-143. (Also in unpublished submission received May 12, 1958 under 400-41; submitted by Uniroyal Chemical, Bethany, CT; CDL:009740-A)
00121603	Uniroyal Chemical (1978) [Royal MH-30 Residue in Potatoes and Potato Chips]. (Compilation; unpublished study received Sep 7, 1978 under 400-84; CDL:235113-A)
00121605	Uniroyal Chemical (1979) Summary of Royal MH-30 Residue Data. (Compilation; unpublished study received Jun 29, 1979 under 400-84; CDL:238717-A)
00122361	Uniroyal Chemical (1970) Summary of Residue Data: [Royal MH-30]. (Compilation; unpublished study received Jun 2, 1975 under 400-84; CDL:101097-B)
00122363	Uniroyal Chemical (1956) Onions: [Sprayed with MH-30]. (Unpublished study received May 7, 1959 under 400-41; CDL:120013-A)
00122364	Uniroyal Chemical (1953) Analysis of Potatoes for Diethanolamine Residues from MH-30. (Unpublished study received Feb 24, 1958 under 400-67; CDL:120039-A)
00122366	Anglin, C.; Mahon, J. (1953?) A Modified Procedure for Detecting Maleic Hydrazide Residues in Plant Material. (Unpublished study received on unknown date under unknown admin. no.; prepared by Canada, Dept. of National Health and Welfare, submitted by ?; CDL:124447-A)
00122390	Meck, R.; Smyser, B.; Smith, A. (1978) The Environmental Studies on Maleic Hydrazide. (Unpublished study received Feb 9, 1978 under 400-41; submitted by Uniroyal Chemical, Bethany, CT; CDL: 232908-A)

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00122399	Nooden, L. (1975) The mode of action and metabolism of maleic hydrazide. Environ. Qual. Saf. 3:473-476. (Also in unpublished submission received Feb 9, 1978 under 400-41; submitted by Uniroyal Chemical, Bethany, CT; CDL:232908-J)
00124739	Kuc, W. (1977) The Acute Toxicity of MH Technical GMS 479 BL 8721 to the Bluegill Sunfish, Lepomis macrochirus (Rafinesque) UCES Proj. # 11506-29-10. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Union Carbide Corp., submitted by Uniroyal Chemical, Bethany, CT; CDL:232653-A)
00124740	Calmbacher, C. (1977) The Acute Toxicity of MH Technical GMS 479, BL 8721 to the Rainbow Trout, Salmo gairdneri (Richardson): UCES Proj. # 11506-29-10. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Union Carbide Corp., submitted by Uniroyal Chemical, Bethany, CT; CDL:232653-B)
00124741	Vilkas, A. (1977) The Acute Toxicity of MH Technical to the Water Flea, Daphnia magna straus: UCES Proj. # 11506-29-10. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Union Carbide Corp., submitted by Uniroyal Chemical, Bethany, CT; CDL:232653-C)
00124742	Fink, R.; Beavers, J.; Brown, R. (1977) Acute Oral LD50--Mallard Duck: MH Technical: Proejct No. 117-130. Final rept. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Wildlife Internationl Ltd., submitted by Uniroyal Chemical, Bethany, CT; CDL:232653-D)
00124883	Jagannath, D. (1978) Sex-linked Recessive Lethal Assay in Drosophila: Evaluation of Maleic Hydrazide ... Technical in Distilled Water 26.78% (W/V): LBI Project No. 20906. Final rept. (Unpublished study received Feb 27, 1978 under unknown admin. no.; prepared by Litton Bionetics, Inc., submitted by Uniroyal Chemical, Bethany, CT; CDL:249368-A)
00125636	Uniroyal Chemical (1976?) [Residues of Maleic Hydrazide]. (Compilation; unpublished study received Feb 16, 1978 under unknown admin. no.; CDL:249370-B)

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00125641	Frear, D.; Swanson, H. (1976?) Behavior and Fate of [14C] Maleic Hydrazide in Tobacco Plants. (Unpublished study received Feb 16, 1978 under unknown admin. no.; prepared by U.S. Agricultural Research Service, Metabolism and Radiation Research Laboratory, submitted by Uniroyal Chemical, Bethany, CT; CDL: 249370-L)
00126033	Fink, R.; Beavers, J.; Brown, R. (1977) Eight-day Dietary LC50--Bobwhite Quail: MH Technical: Project No. 117-129. Final rept. (Unpublished study received Jan 6, 1978 under 400-84; prepared by Wildlife International Ltd., submitted by Uniroyal Chemical, Bethany, CT; CDL:232653-E)
00128720	Mackenzie, K.; Dupre, M.; MacWilliams, P.; et al. (1983) Two-generation Reproduction Study with KMH in Rats: Study No. 81065. Final rept. (Unpublished study received Jun 16, 1983 under 400-84; prepared by Hazleton Raltech, Inc., submitted by Uniroyal Chemical, Bethany, CT; CDL:250522-A)
00128721	Schardein, J.; Aldridge, D.; Allen, S.; et al. (1983) Teratology Study in Rabbits with Potassium Salt of Maleic Hydrazide: 399-051. (Unpublished study received Jun 16, 1983 under 400-84; prepared by International Research and Development Corp., submitted by Uniroyal Chemical, Bethany, CT; CDL:250523-A)
00141353	Uniroyal, Inc. (1978) Rebuttal to Rebuttable Presumption against Registration of Maleic Hydrazide: Volume I. Unpublished compilation. 523 p.
00143322	Uniroyal Chemical Co. (19??):Environmental Data on Maleic Hydrazide in Soil and Water:. Unpublished study. 4 p.
00146141	Beavers, J. (1985) An Acute Oral Toxicity Study in the Mallard with Potassium Salt of Technical Maleic Hydrazide: Final Report: Project. No. 117-146. Unpublished study prepared by Wildlife International, Ltd. 15 p.
00146142	McAllister, W.; Cohle, P. (1984) Acute Toxicity of Potassium Salt of Technical Maleic Hydrazide to Rainbow Trout (Salmo gairdneri): 32250. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 53 p.

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MRID	CITATION
00147000	Beavers, J. (1985) A Dietary LC50 Study in the Mallard with Potassium Salt of Technical Maleic Hydrazide: Final Report: Project No. 117-145. Unpublished study prepared by Wildlife International, Ltd. 13 p.
00151951	Lengen, M.; Frederick, C. (1985) The Photolysis of (Potassium Salt) - Maleic Hydrazide in Aqueous Solution and on Soil: Project No. 8573. Unpublished study prepared by Uniroyal Chemical. 13 p.
00151952	Lengen, M. (1985) Mobility Studies of (Potassium Salt) - Maleic Hydrazide on Soils: Project No. 8574. Unpublished study prepared by Uniroyal Chemical. 14 p.
00163301	Cable, R. (1986) Octanol/Water Partition Coefficient of Maleic Hydrazide. Unpublished study prepared by Drexel Chemical Company. 55 p.
00165460	Uniroyal Chemical Co., Inc. (1970) [Efficacy Data of MH-30 and Other Pesticides for Control of Suckers on Tobacco]. Unpublished compilation. 26 p.
05006328	Cohen, S.Z.; Zweig, G.; Law, M.; Wright, D.; Bontoyan, W.R. (1978) Analytical determination of N-nitroso compounds in pesticides by the United States Environmental Protection Agency--a preliminary study. Pages 333-342, In Environmental Aspects of N-Nitroso Compounds. Washington, D.C.: Environmental Protection Agency. (IARC scientific publications, vol. 19)
40034802	Lengen, M.; Batorewicz, W. (1986) Field Dissipation of Maleic Hydrazide—Salt Formulation—Royal MH-30 SG: Project No. 8575. Unpublished study prepared by Uniroyal Chemical Co., Inc. 75 p.
40149901	Lengen, M. (1986) Anaerobic Soil Metabolism of :Carbon 14: Maleic Hydrazide--Potassium Salt: [Revised]: Project No. 8634. Unpublished study prepared by Uniroyal Chemical Co., Inc. 25 p.
40663501	Cabral, J.; Ponomarkov, V. (1982) Carcinogenicity Study of the Pesticide Maleic Hydrazine in mice. Toxicology 24 (2):169-173.

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ **1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:**

☐ **2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:**

NAME OF OTHER REGISTRANT

☐ **3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:**

☐ **4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):**

☐ **5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)**

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

Form Approved. OMB No. 2070-0057. Expires 11-30-88.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify __ALL__ four items)

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Registration Standard for ______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID Number or EPA Accession Number	I am complying with data requirements by: Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Part 158 Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	 Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are _____________ .

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ________________ ______________________________
(Typed)

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